

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 00D-1681]

DMB

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Certifier	SR Reese

**Draft Guidance on Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies; Availability; Extension of Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; extension of comment period.

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**SUMMARY:** The Food and Drug Administration (FDA) is extending to April 30, 2001, the comment period for the draft guidance entitled "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies" that appeared in the **Federal Register** of January 4, 2001 (66 FR 801). FDA is taking this action in response to a request for an extension.

**DATES:** Submit written comments on the draft guidance by April 30, 2001. General comments on agency guidance documents are welcome at any time.

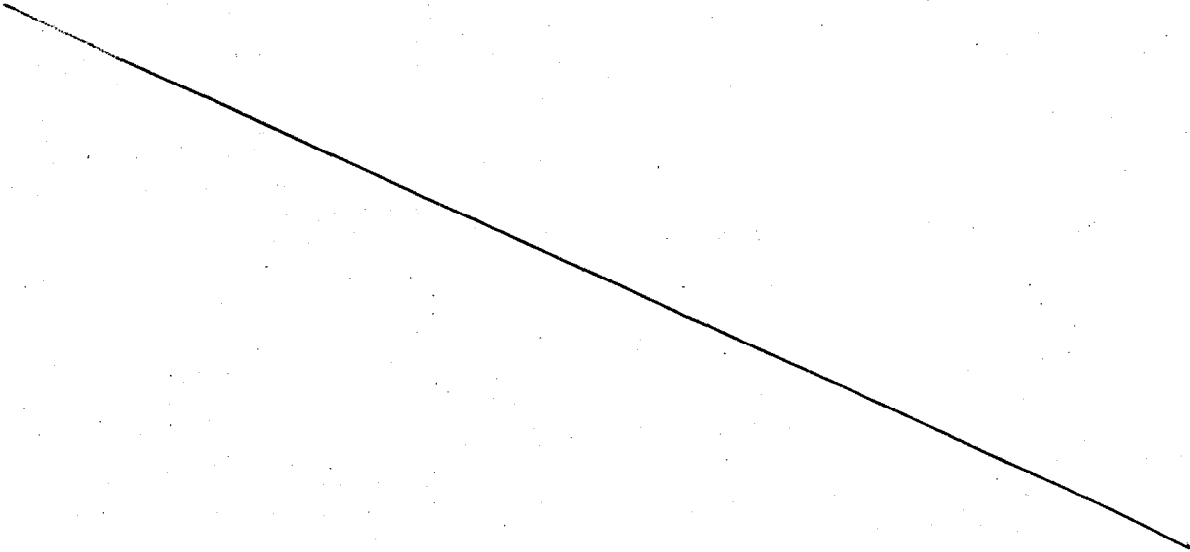
**ADDRESSES:** Copies of this draft guidance are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your request. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Rose E. Cunningham, Executive Operations (HFD-06), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-6779.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 4, 2001 (66 FR 801), FDA published a notice announcing the availability of a draft guidance document entitled "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies." This draft guidance updates the notice of availability entitled "Potassium Iodide as a Thyroid-Blocking Agent In a Radiation Emergency: Final Recommendations On Use," published in the **Federal Register** of June 29, 1982 (47 FR 28158). In this draft guidance, FDA maintains its position that potassium iodide is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland, under certain specified conditions of use, and thus to lessen the risk of thyroid cancer in the event of a radiation emergency.

FDA received an e-mail request, dated January 4, 2001, requesting that the agency extend the comment period on the draft guidance by 60 days, allowing 90 days for comments. Because the draft guidance introduces several new recommendations, the agency has decided to extend the comment period on the draft guidance to April 30, 2001, to allow the public more time to review and comment on its contents.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance document by April 30, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The draft guidance



document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 2, 2001  
February 2, 2001



Ann M. Witt  
Acting Associate Commissioner for Policy

[FR Doc. 01-???? Filed ??-??-01; 8:45 am]

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